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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,540	TACHINO, ATSUSHI	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *3 and 6-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1.00.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on July 15, 2005 is acknowledged. The traversal is on the ground(s) that the groups are independent and that there is no serious search burden. This is not found persuasive because the inventions are related as distinct methods because they are drawn to different method steps; reagents; functions and those differences result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification beginning at page 9 states that the methods are separate and distinct, contrary to applicants assertions. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Moreover, the methodology and materials necessary for the pretreatment of saliva differ significantly.

Applicants' argue that there would be no serious burden on the Examiner to search for the other groups. However, in the instant case, the kits and methods are unrelated and distinct and the search of each is not coextensive. In cases such as this one where descriptive pre-treatment kit information is provided, the reagents are searched in appropriate databases. There is search burden also in the non-patent literature. Thus, a search drawn to a pretreatment kit and method sodium hydroxide, tartaric acid, a nonionic surface active agent and tris(hydroxymethyl) aminomethane is not necessary for a determination of novelty and unobviousness of the method of group II which comprises sodium hydroxide, tartaric acid and a nonionic surface active agent

in an amount of 5 to 25% by weight. This search requires an extensive analysis of the art retrieved in a search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search all the kits and methods together. It is also noted that applicant has not submitted evidence or clearly admitted on the record that the kits and method are obvious variants, which further implies that an unduly burdensome search is required to search each separate and distinct method and kit Therefore, the requirement is still deemed proper and is made FINAL.

2. Claims 3 and 6-11 have been withdrawn. Claims 1-2 and 4-5 are under consideration in this office action.

Specification

3. The disclosure is objected to because of the following informalities:

A) Throughout the specification, several words are merged as one. For example see page 12, line 6; page 41, line 6; or page 47, line 6.

B) Throughout the specification, the bacteria "*Streptococcus mutans*" is referred to as "mutan streptococcus". Therefore, appropriate correction is required throughout the specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

5. Claims 4 and 5 are dependant on nonelected claim 3. Therefore appropriate correction is required.

6. Claim 5 is objected to because of the following informalities: Claim 5 refers to CHAPS 3,3,-cholamide-propyl dimethyl ammoniol-1-propane sulfonate or CHAPSO 3,3,-cholamide-propyl dimethyl ammoniol-1-hydroxypropane sulfonate. However the reagents should be written as 3,3,-cholamide-propyl dimethyl ammoniol-1-propane sulfonate (CHAPS) or 3,3,-cholamide-propyl dimethyl ammoniol-1-hydroxypropane sulfonate (CHAPSO). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim states that the kit may comprise a mixture of two or more kinds of amphoteric surface active agents selected from CHAPS or CHAPSO. However it is unclear how a person can mix more than two kinds of agents if there are only two options. Therefore, clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al., (application number JP 2001186626; publication number 2002-35799, filed June 6, 2001, published Dec. 13, 2002) [see also EP 1,248,106 A1 as a translation] in view of Ha et al., (US Patent 5,817,297 published Oct. 6,1998).

The claims are drawn to a pretreatment kit for saliva comprising: (A) an aqueous solution of sodium hydroxide having a concentration of 0.01 to 10 mo1/L, (B) an aqueous solution of tartaric acid and/or citric acid having a concentration of 0.01 to 3 mol/L,

and (C) a nonionic surface active agent and/or an amphoteric surface active agent, the component (C) being mixed with at least one of the components (A) and (B), being provided separately from the components (A) and (B), and at least one substance selected from the group consisting sodium chloride, potassium chloride, calcium chloride, magnesium chloride, magnesium sulfate and manganese sulfate being contained in at least one of the components (A), (B) and (C) in an amount of

5 to 25% by weight. The dependant claims are drawn to the kit further comprising tris(hydroxymethyl)aminomethane or specific nonionic or amphoteric surface active agents.

Okada et al., teach a saliva pre-processing kit. The kit contains an aqueous solution constructed of (A) sodium hydroxide, (B) tris(hydroxymethyl)aminomethane buffer solution containing tartaric acid and/or citric acid; and a nonionic surfactant and/or amphoteric surfactant wherein the surfactant is previously mixed with the aqueous solution and/or buffer solution or is prepared separately from the aqueous solution and the buffer solution (col. 3, lines 13-22). The nonionic surfactant is one member or a mixture of two or more members selected from the group consisting of polyethylene glycol monooctylphenyl ether, n-octyl-B-D-glucoside, n-heptyl-B-D-thioglucoside, n-octyl-B-D-thioglucoside, nonylphenoxypolyethozyethanol and polyoxyethylene sorbitan monooleate (col. 3, lines 32-38). The amphoteric surfactant is one member or a mixture of two members selected from the group consisting of 3,3,-cholamide-propyl dimethyl ammoniol-1-propane sulfonate (CHAPS) or 3,3,-cholamide-propyl dimethyl ammoniol-1-hydroxypropane sulfonate (CHAPSO) (col. 3, lines 40-44). The preferred concentrations of sodium hydroxide, tartaric acid and citric acid are 0.01M or more (col. 5, lines 13-15). Thus, the disclosed ranges are encompassed within the instantly claimed ranges which requires having concentrations of 0.01 to 10 mol/L and 0.01 to 3 mol/L for sodium hydroxide, tartaric acid and/or citric acid respectively. When concentrations are lower, the intended effects tend not to be achieved (col. 5, lines 15-21). However, higher concentrations of sodium hydroxide, tartaric acid and citric acid are more advantageous,

since it increases detection sensitivity (col. 5, lines 21-24). Okada et al., however, do not teach a kit comprising sodium chloride.

Ha et al., (US Patent 5,817,297) teach compositions for enhancing oral hygiene comprising acidity regulating agents such as citric acid and tartaric acid (col. 4,lines 33-36). The oral composition can further include sodium chloride for the purpose of alleviating gingival inflammation and bactericidal activity, in an amount of 3 to 35% weight percent (col. 6, lines 19-23). This is within the instantly claimed range.

Therefore it would have been prima facie obvious at the time of applicants' invention to modify the pretreatment kit of Okada et al., to incorporate the sodium chloride as taught by Ha et al., because Ha et al., already teach the use of sodium chloride within the desired range. One would have a reasonable expectation of success because no more than routine skill would have been required to incorporate a bactericidal agent into a saliva pretreatment when similar compositions are known in the art to comprise agents which alleviate gingival inflammation. Moreover, one of ordinary skill in the art would have been motivated to incorporate sodium chloride into the pretreatment kit because of its desirable anti-gingival and bactericidal activity.

Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Matsumoto et al., (Pub. No 2002/0197738) teach pretreatment methods for saliva. Okada et al., (US Patent 6,897,037) teach pre-treatment kits for saliva. Pan et al., (US Patent 5,147,632) teach anti-plaque compositions comprising

pharmaceutically acceptable salts of acids such as citric and tartaric acid, along with nonionic and amphoteric surfactants. Suga et al., (US Patent 5,882,631) teach compositions comprising nonionic surfactant, a pH balanced agent, such as citric acid, tartaric acid and sodium hydroxide from 0.01 to 2% by weight, and may further comprise sodium chloride. Tuompo et al., (US Patent 5,910,420) teach methods and kits for compositions comprising CHAPS or CHAPSO used to remove biofilms while not hindering the growth of the microorganism.

Conclusion

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

September 19, 2005